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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,961	07/11/2005	Charles C. Hart	2877-USP-PCT-US	8849

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,961	<b>Applicant(s)</b> HART ET AL.	
	<b>Examiner</b> Lindsey Bachman	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-11-05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. The use of the trademark KRATON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.
2. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 14, 26 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 14 uses the trademark KRATON and does not comply with the requirements of 35 U.S.C. 112, second paragraph, *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The scope of the claim is uncertain because the trademark cannot be used to properly identify any particular material or product. See MPEP 2173.05(u).

8. Further regarding claim 14, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

9. Claim 26 recites the limitation "the first bent extension" and "the second bent extension" in line 6. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 32 recites the limitation "traction" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claims 1-8, 11, 18-25, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kees (US Patent 3,827,438).**

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13. Regarding Claim 1 and 41, Kees'438 discloses a one-piece clip having a first jaw (18) having a distal end (left of number 18 in Figure 1) and a proximal end (near element 10 in Figure 1), a second jaw (19) having a distal end (left of number 19 in Figure 1) and a proximal end (near element 10 in Figure 1) and opposed to first jaw (18), a first arm (13) attached to the proximal end of the first jaw (18) to pressably close or open the first jaw, a second arm (14) attached the proximal end of the second jaw (19), wherein the clip is constructed from a single wire (column 1, line 10-13).

14. Regarding Claim 2, Kees'438 discloses that the arms are resiliently pressed against each other in the closed position (see Figure 1).

15. Regarding Claim 3 and 42, Kees'438 discloses a tensioning device (12) connected to the first jaw (18) and the second jaw (19) to bias the jaws into the closed position (see Figure 1 and column 2, lines 12-15).

16. Regarding Claim 4, Kees'438 discloses that the tensioning device is a coil (12) having at least 1 turn (see Figure 2).

17. Regarding Claim 5, the device taught by Kees'438 is capable of having the tension, strength, and holding characteristics of the tensioning device varied based on the number of turns in the central coil and the hardness/temper of the wire because it is of the same design, and made with metal which can have the material properties/characteristics modified in similar ways (such as tempering, type of metal used, etc.).

18. Regarding Claim 6, Kees'438 discloses that the wire has a cross-section having a geometric shape.

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19. Regarding Claim 7, Kees'438 discloses that the wire is folded in one plane (see Figure 1 and 2).

20. Regarding Claim 8, the device taught by Kees'438 is capable of being curved, bent, or shaped to provide access to a specific area of a procedure because it is made of a similar material (metal, which is malleable) and its intended use is for the same type of procedure (aneurysm clip).

21. Regarding Claim 11, Kees'438 discloses that the clip has an atraumatic distal end (tip left of numbers of 18 and 19 in Figure 1).

Regarding Claim 18, Kees'438 discloses that the clip is used as an aneurysm clamp (column 1, lines 3-4).

22. Regarding Claim 19, the clip taught by Kees'438 is inherently disposable.

23. Regarding Claim 20, the clip taught by Kees'438 is inherently reusable.

24. Regarding Claim 21, the device taught by Kees'438 is capable of being formed from stamping because it is made from a flat ribbon of metal (column 1, lines 10-12).

25. Regarding Claim 22, the device taught by Kees'438 is formed from a pre-formed ribbon of metal (column 1, lines 10-12).

26. Regarding Claim 23, the device taught by Kees'438 is capable of being formed from a die-cut perform because it is made of a flat ribbon of metal that is capable of being die-cut.

27. Regarding Claim 24, the device taught by Kees'438 is capable of being photo-chemically cut, etched pre-form, or sheet of preformed ribbon because it is made from a the same material (flat ribbon of metal).

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28. Regarding Claim 25, the device taught by Kees'438 is capable of being formed from a plurality of pre-formed generated from a plurality of pre-forms generated on a single sheet because it is made from the same material (flat ribbon of metal).

**29. Claims 26, 28, 29, 30, 31, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt, et al. (US Patent 5,758,420).**

30. Schmidt'420 discloses a method for manufacturing an aneurysm clip that includes winding a single wire (12) around a mandrel in order to form a central coil (22), a first extension (26), and a second extension (34) (column 9, lines 55-67). Next, the first extension (26) is bent back on itself to form a first jaw (32) then bending the second extension back on itself to form a second jaw (40). Then, returning the first bent extension (32) and the second bent extension (40) back to the central coil (22) so that the first and second extensions extend rearward in a direction opposite of the first and second jaws to form a first handle portion (26) and a second handle portion (34).

31. Regarding Claim 28, Schmidt'420 discloses that the first (32) and second (40) bent extensions include an atraumatic distal end (column 1, lines 65-67).

32. Regarding Claim 29, Schmit'420 discloses that the first and second bent extensions (32, 40) are formed to rest upon the coil (see Figure 10).

33. Regarding Claim 30, the method taught by Schmidt'420 inherently allows for configuring the clip for specific areas of a procedure (column 12, lines 5-11).

34. Regarding Claim 31, Schmidt'420 teaches a method of manufacturing that includes cold drawing and coining at high temperatures to create an aneurysm clip that creates a surface layer that remains free of microcracks, which can propagate into

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traumatic cracks. Thus, the manufacturing method taught by Schmidt'420 keeps the clip safe for medical applications.

35. Regarding Claim 39, Schmidt'420 discloses that his steps may be modified in order to facilitate precision manufacturing (column 3, lines 28-29).

36. Regarding Claim 40, Schmidt'420 teaches his manufacturing processes uses a cylindrical rod (column 3, lines 11-13).

**37. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Vien (FR 1.029.119).**

38. Vien'119 discloses a clip made of a single wire comprises a first jaw (2), a second jaw (second element 2), a first arm (3), and a second arm (second element 3), wherein the clip is constructed from a single wire (Figure 1).

39. Regarding Claim 9, Vien'119 discloses that the first arm and second arm (3) have a ring shaped proximal tip to enhance grip (see Figure 1).

40. Regarding Claim 10, the ring shaped proximal tip taught by Vien'119 is capable of being attached to a tether or suture to allow for easy tracking of the tip.

### ***Claim Rejections - 35 USC § 103***

41. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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42. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**43. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kees'438, as applied to Claim 1, in further view of Davis, et al. (US Patent 6,527,786).**

44. Kees'438 teaches the limitations of Claims 12-14 except for the use of serrated jaws and a polymer coating on the jaws, and the use of another coating on the remainder of the clip.

45. Davis'786 teaches a ligating clip that can have either serrated jaws or a sticky coating in order to improve the clip's traction (column 5, lines 63-68). Soft elastomers are well known in the art to be a sticky coating. Regarding Claim 15, Davis'786 discloses that the clip can be made out of metal, like stainless steel or titanium. It is well known in the art that these materials comprise a thin layer of oxide coating that makes them less prone to corrosion. Therefore it would have been obvious to one skilled in the art at the time the invention was made to improve traction on the jaws of a clip by adding serrations or coating the jaws. And it would have been obvious to one skilled in the art to claim that the remainder of the clip is inherently coated with a thin oxide coating when it is made out of metal.

**46. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kees'438, as applied to Claim 1, in further view of Schmidt'420.**

47. Kees'438 discloses the limitations of Claim 16, except for the use of a tool to reshape the jaws of the clip.

48. Schmidt'420 discloses the use of a mandrel to shape the clip (column 9, lines 55-67). Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a mandrel to customize the shape of the clip in order to use it in various applications.

**49. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kees'438, as applied to Claim 3, in further view of Yoon (US Patent 5,217,473).**

50. Schmidt'420 teaches the limitations of Claim 3, except for the use of a traction rod to deploy the clip.

51. Yoon'473 discloses the use of a rod (14) that can be used to place the tensioning device (12) of the clip (10) at the desired location during the procedure in order to place in the clip in places accessible to the hands. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a rod to aid in deployment of the clip in hard to reach locations in the body.

**52. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt'420, as applied to Claim 26, in further view of Vien'119.**

53. Schmidt'420 teaches the limitations of Claim 27 except for bending the first and second proximal portions to enhance grip. Vien'119 teaches that the first and second handle portions are bent back to form a grip, in order to provide a larger surface for the

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user to grip as shown in Figure 1. Therefore it would have been obvious to one skilled in the art at the time the invention was made to bend back the first and second handle portions to create a larger gripping area.

<sup>32</sup>  
**54. Claim ~~31~~<sup>32</sup>-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt'420, as applied to Claim 31, in further view of Davis'786.**

55. Schmidt teaches the limitations of Claim 31, except for the use of a polymer coating and the use of reusable traction-enhancing inserts.

56. Regarding Claim 33, Davis'786 teaches a ligating clip that can have a sticky coating in order to improve the clip's traction (column 5, lines 63-68). Soft elastomers are well known in the art to be a sticky coating. Regarding Claim 32, the device taught by Davis'786 inherently separates the traction force from the force required to occlude the vessel. Regarding Claim 34, Davis'786 discloses that the clip can be made out of metal, like stainless steel or titanium. It is well known in the art that these materials comprise a thin layer of oxide coating that makes them less prone to corrosion.

Therefore it would have been obvious to one skilled in the art at the time the invention was made to improve traction on the jaws coating the jaws with a polymer. Regarding Claim 35 and 36, if a polymer coating is placed over the jaws, it is removable, and therefore must be reusable and disposable. Therefore it would have been obvious to one skilled in the art at the time of the invention to place a reusable coating over the jaws in order to improve the traction grip.

**57. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt'420, as applied to Claim 26, in further view of Vien'119.**

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58. Schmidt'420 teaches the limitations of Claim 37 except for the use of a ring-shaped proximal tip. Regarding Claim 37, Vien'119 discloses that the first arm and second arm (3) have a ring shaped proximal tip to enhance grip (see Figure 1).

Regarding Claim 38, the ring shaped proximal tip taught by Vien'119 is capable of being attached to a tether or suture to allow for easy tracking of the tip. Therefore it would have been obvious to one skilled in the art at the time the invention was made to bend back the first and second handle portions to create a larger gripping area.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Imb

A handwritten signature in black ink, appearing to read "M J Hayes", is positioned above the printed name.

MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER